DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 25, 2015

Stryker Sustainability Solutions
Mr. Scott English
Staff Regulatory Affairs Specialist
1810 West Drake Drive
Tempe, Arizona 85283

Re: K150538
Trade/Device Name: Reprocessed LigaSure Impact™ Curved, Large Jaw, Open Sealer/Dividers
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NUJ
Dated: May 20, 2015
Received: May 21, 2015

Dear Mr. English:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Reprocessed Single Use Device Models Included in Clearance:

Device Model	Device Name	Original Manufacturer
LF4318	LigaSure Impact™ Curved, Large Jaw, Open Sealer/Divider	Covidien

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150538

Device Name
Reprocessed LigaSure Impact™ Curved, Large Jaw, Open Sealer/Dividers

Indications for Use *(Describe)*
The Reprocessed LigaSure Impact™ Curved, Large Jaw, Open Sealer/Divider LF4318 is a dedicated bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels is desired. The Reprocessed LigaSure Impact™ LF4318 is intended to be used with the ForceTriad™ Energy Platform to cut and seal vessels, and to cut, grasp, and dissect tissue during surgery.

The indications for use include open procedures (general, urologic, vascular, thoracic, and gynecological) where ligation and division of vessels is performed. These procedures include vaginal hysterectomies, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. The Reprocessed LigaSure Impact™ LF4318 can be used on vessels (arteries, veins, pulmonary vasculature, and lymph) up to and including 7 mm and tissue bundles.

The LigaSure™ system has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure™ system for these procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K150538

SECTION 5: 510(k) SUMMARY

Submitter:
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Date of Preparation: March 2, 2015

Name of Device:

Trade/Proprietary Name: Reprocessed LigaSure Impact™ Curved, Large Jaw, Open Sealer/Divider

Common Name: Bipolar Electrosurgical Open and Laparoscopic Instruments

Classification Name: Electrosurgical, Cutting & Coagulation Accessories, Laparoscopic & Endoscopic, Reprocessed (21 CFR§878.4400, Product Code NUJ, Class II)

Predicate Devices:

Model Number	510(k) Number	510(k) Title	Original Manufacturer
LF4318	K123444	LigaSure Impact Curved, Large Jaw, Open Sealer/ Divider	Covidien

Device Description:

The Reprocessed LigaSure Impact™ Curved, Large Jaw, Open Sealer / Divider is a hand-held bipolar electrosurgical instrument designed exclusively for use with the ForceTriad™ Energy Platform to seal and divide vessels (including pulmonary) up to and including 7 mm in diameter, tissue bundles, and lymphatics during open general surgical procedures. The ForceTriad's tissue-fusion (LigaSure™) mode is designed to deliver precise energy to tissue for a controlled time period to achieve complete and permanent tissue fusion. A blade within the instrument is surgeon actuated to divide tissue.

The instrument has a shaft diameter of 13.5 mm (square), shaft length of 18 cm, and jaw length of 36 mm. The following controls are located on the instrument handle:

- A lever for opening and closing the instrument jaws. The mechanism incorporates a latch to hold the jaws in the closed position during vessel sealing and cutting.
- An activation button for generator power to initiate vessel sealing.
- A trigger for actuating the cutter.
- A knob to rotate the instrument jaws.

All controls can be operated with either the right or left hand. Vessel sealing can be initiated using the activation button or utilizing a footswitch connected to the generator. The instrument attaches to the ForceTriad™ Energy Platform via a ten-foot cord with a LigaSure™ cable connector that identifies the instrument type to the generator.

The instrument is compatible with the Covidien™ ForceTriad™ Energy Platform running software version 3.50 or greater.

The scope of this submission only includes the reprocessed Covidien™ sealer/divider device and not the ForceTriad™ Energy Platform that is used to power the device or the footswitch that connects to the generator. Stryker Sustainability Solutions does not reprocess or market the generator or footswitch.

Intended Use:

The Reprocessed LigaSure Impact™ Curved, Large Jaw, Open Sealer/Divider LF4318 is a dedicated bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels is desired. The Reprocessed LigaSure Impact™ LF4318 is intended to be used with the ForceTriad™ Energy Platform to cut and seal vessels, and to cut, grasp, and dissect tissue during surgery.

The indications for use include open procedures (general, urologic, vascular, thoracic, and gynecological) where ligation and division of vessels is performed. These procedures include vaginal hysterectomies, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. The Reprocessed LigaSure Impact™ LF4318 can be used on vessels (arteries, veins, pulmonary vasculature, and lymph) up to and including 7 mm and tissue bundles.

The LigaSure™ system has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure™ system for these procedures.

Summary of Technological Characteristics:

The design, materials, and intended use of Reprocessed LigaSure Impact™ Curved, Large Jaw, Open Sealer/Divider is equivalent to the predicate device. The mechanism of action of the reprocessed device is identical to the predicate device in that the same standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Stryker Sustainability Solutions' reprocessing of LigaSure Impact™ Curved, Large Jaw, Open Sealer/Divider includes removal of adherent visible soil and decontamination. Each individual device is tested for appropriate function of its components prior to packaging and labeling operations.

Performance Data:

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed LigaSure Impact™ Curved, Large Jaw, Open Sealer/Divider. This included the following tests:

- Biocompatibility
- Validation of Reprocessing
- Sterilization Validation
- Functional Performance Tests
- Electrical Safety Testing
- Electromagnetic Compatibility Testing
- Packaging Validation

The functional performance testing involved electrical safety and electromagnetic compatibility testing in accordance with IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-2, and verification/comparative testing (to the predicate device). The bench testing involved evaluation of the device's performance and ability to seal and divide vessels up to 7mm, including: burst pressure, thermal spread, max jaw tip temperature, jaw cooling time, device functionality, and device reliability testing.

Acute and chronic pre-clinical testing was conducted to evaluate thermal spread and the ability to achieve hemostasis of vessels and tissues.

The performance testing demonstrates that reprocessed devices are as safe and effective as the predicate and operate as originally intended.

Conclusion:

Stryker Sustainability Solutions concludes that the Reprocessed LigaSure Impact™ Curved, Large Jaw, Open Sealer/Divider is at least as safe and effective to the predicate device as described herein.